

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 29

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DOUGLAS J. M. ALLEN and KEVIN M. NEPVEUX

Appeal No. 95-4433
Application No. 07/994,040¹

ON BRIEF

Before GARRIS, OWENS and WALTZ, Administrative Patent Judges.

GARRIS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal from the final rejection of claims 1 through 3 which are all of the claims in the application.

¹ Application for patent filed December 21, 1992. According to appellants, this application is a continuation of Application 07/449,961 filed December 11, 1989, now abandoned.

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The subject matter on appeal relates to crystalline azithromycin dihydrate and to a method for the preparation thereof. Further details of this subject matter are readily apparent from a review of the appealed claims which read as follows:

1. Crystalline azithromycin dihydrate.
2. A method of preparing crystalline azithromycin dihydrate which comprises crystallization of amorphous azithromycin or azithromycin monohydrate from a mixture of tetrahydrofuran and a (C₅-C₇) aliphatic hydrocarbon in the presence of at least 2 molar equivalents of water.
3. A method of claim 2 wherein the hydrocarbon is hexane.

The references relied upon by the examiner as evidence of obviousness are:

Desposato et al. (Desposato)	4,219,641	Aug.
26, 1980		
Bright	4,474,768	Oct. 2,
1984		

Claims 1 through 3 stand rejected under 35 U.S.C. § 103 as being unpatentable over Bright in view of Desposato.

This rejection cannot be sustained.

On this appeal, the examiner and the appellants have advanced respectively reference evidence of obviousness and declaration evidence of nonobviousness. Accordingly, we will assess the patentability of the here claimed invention under 35 U.S.C. § 103 based upon the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

Example 3 of the Bright reference discloses making a crystalline product said to constitute azithromycin monohydrate² using ethanol and water. Consistent with the appellants' arguments, it is questionable whether one with ordinary skill in the art would have found in the Desposato reference any reason, suggestion or incentive to modify Bright's aforementioned disclosure in such a manner as to obtain a crystalline azithromycin dihydrate as required by appealed claim 1 or a method for the preparation thereof from a mixture of tetrahydrofuran and a (C₅-C₇) aliphatic hydrocarbon in the presence of at least two molar equivalents

² On the record before us, it is undisputed that azithromycin monohydrate constitutes the product of Example 3.

of water as required by appealed claim 2. This is because Desposato, although disclosing the existence of erythromycin dihydrate (see line 6 in column 3), contains no disclosure regarding the crystalline form of this compound much less crystalline azithromycin dihydrate. Similarly, although patentee discloses crystallizing erythromycin ethyl succinate from an aqueous mixture containing tetrahydrofuran as solvent or ethyl acetate as solvent combined with hexane (e.g., see lines 37 through 56 in column 1), Desposato contains no disclosure of using a mixture of tetrahydrofuran and a C₅-C₇ aliphatic hydrocarbon in the presence of at least two molar equivalents of water in order to prepare crystalline azithromycin dihydrate.

As rebuttal evidence, the appellants have advanced a number of declarations. These declarations include the Forcier Declaration signed March 19, 1992 and the Hangac Declaration signed February 16, 1994 which compare respectively the hygroscopicity and stability characteristics of crystalline azithromycin dihydrate and azithromycin monohydrate. Notwithstanding the examiner's criticisms thereof, these declarations quite plainly show that the

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aforementioned characteristics of crystalline azithromycin dihydrate are significantly and unexpectedly superior to those of crystalline azithromycin monohydrate.

Under the circumstances recounted above, it is our determination that the evidence of record, on balance, weighs most heavily in favor of a nonobviousness conclusion. It follows that we cannot sustain the examiner's § 103 rejection of claims 1 through 3 as being unpatentable over Bright in view of Desposato.

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The decision of the examiner is reversed.

REVERSED

	BRADLEY R. GARRIS)	
	Administrative Patent Judge))	
)	
)	
	TERRY J. OWENS)	BOARD OF
PATENT	Administrative Patent Judge))	APPEALS AND
)	INTERFERENCES
)	
	THOMAS A. WALTZ)	
	Administrative Patent Judge))	

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